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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/684,730	10/14/2003	Shalini Sharma	18015-D5	4306
31976	7590	05/10/2004	EXAMINER	
LEWIS J. KREISLER LEGAL DEPARTMENT 930 CLOPPER ROAD GAITHERSBURG, MD 20878			PATEL, SUDHAKER B	
			ART UNIT	PAPER NUMBER
			1624	

DATE MAILED: 05/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/684,730

Applicant(s)

SHARMA, SHALINI

Examiner

Sudhaker B. Patel, D.Sc.Tech.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 April 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) _____ is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 April 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Applicants' communication paper dated 4/12/04 is acknowledged.

Applicant's arguments and remarks have been reviewed and reconsidered, but not found persuasive for allowance of this application at this stage for the reasons stated below, and reasons already stated in earlier Office Action paper dated 3/23/04.

1. **Withdrawal of rejections:** Rejections under 35 U.S.C.103 (a) are now withdrawn because Nussbaumer et al (DE 3720317 dated 12/1988) does not teach making of 2,6-difluorophenyl-4-oxobutyric acid and its derivatives.

2. **Rejections maintained:** The rejections made under 35 U.S.C. 112 paragraph second are maintained further because of the reasons already mentioned in above stated Office paper. Applicants' claims are related to derivatives of 2,6-difluorophenyl-4-oxobutyric acids, which are not claimed as specific chemical compounds, but also as biologically active agents without disclosing their specific and exact biological activity.

3. Applicant's arguments do not comply with 37 CFR 1.111(c) because they do not clearly point out the patentable novelty which he or she thinks the claims present in view of the objections made. Further, they do not show how the amendments avoid such references or objections. Citations from the dictionary defining the term(s) "Agent" & "Biologically Active Agent" as compound without disclosing the exact and definite biological activity are not sufficient for the withdrawal of the rejections for claims 1-3 made under 35 U.S.C. 112 paragraph second.

4. **New Rejections:**

Claim Rejections - 35 USC § 102 :The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3 are rejected under 35 U.S.C. 102(b) as being anticipated by Giordani et al (WO9717317 dated 5/1997). Giordani teaches making of Compounds of Formula IV (see pages 13, 15) and Compounds of Claim1, Formula (I)(see page 44). The ref.'317 also teaches biological utility as kynurenine-3-hydroxylase inhibitor. The reference compounds have a core:," Halogenated-phenyl-CO-CR₂R₄-CR₃R₁-CO-R wherein R is OH, R₁, R₂, R₃, R₄ are H, and Y is H/alkyl, and Z/X can be fluorines as claimed herein.

5. ***Claim Rejections - 35 USC § 103***: The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 1-3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Giordani et al (WO 9717317 dated 5/1997). Giordani teaches making of Compounds of Formula IV (see pages 13, 15) and Compounds of Claim1, Formula (I)(see page 44). The ref.'317 also teaches biological utility as kynurenine-3-hydroxylase inhibitor. The reference compounds have a core: "Halogenated-phenyl-CO-CR₂R₄-CR₃R₁-CO-R wherein R is OH, R₁, R₂, R₃, R₄ are H, and Y is H/alkyl, and Z/X can be fluorines as claimed herein.

8. Giordani differs from the instant compounds by claiming dihalogenated as well as polyhalogenated compounds and their use as pharmaceuticals.

It would have been obvious to one having ordinary skill in the art at the time of invention to prepare instant compounds by modifying or replacing hydrogen atom of phenyl ring by fluorine atoms and make various combinations as 2,6-difluoro, 2,4-difluoro and others to prepare the 2,6-difluorocompound of a benzene derivative, and try out the use/utility as a pharmaceutical by using the conventional chemistry knowledge. The motivation stems from the expectation of making compounds having equal or better pharmaceutical agent.

"Structural relationships may provide the requisite motivation or suggestion to modify one compound to obtain another compound(s)". For example, one compound may suggest its homologue/isomer, because homology/isomer often have similar properties, and therefore, chemists of ordinary skill would ordinarily contemplate making them to try to obtain compounds with improved properties, or merely to satisfy their production goals.

9. Process/use which, from the results obtained, is analogous to a prior art(s) is not patentable merely because the product thereof is novel and patentable. *Clinical Products, Ltd. Vs. Brenner. Comr. Pats.* See also *In re Kirkhoven* (CCPA 1980)626 F2d 846, 205 USPQ 1069.

10. The other prior art reference Berryman et al ((WO 9505376 dated 2/23/1995, also cited as Chemical Abstract DN 128:48214) teaches a final compound with CAS RN # 169803-96-7 with a core: "2,6-difluorophenyl-CO-CH₂-CH (COOMe)-1,3-Benzodioxole".

The ref.'376 does suggest making of chemical compound(s)/derivatives with a core: "2,6-difluorophenyl-4-oxo-butyric acid". The ref. differs by having H of -CH₂-bridge modified by a ring, which is benzodioxole.

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It would have been obvious to one having ordinary skill in the art at the time of invention to prepare instant compounds by modifying or replacing the Benzodioxole ring of the chain/bridge (= -CH-ring/cycle) by H atom and make various combinations of 2,6-difluoro methyl or alkyl esters and try out the use/utility as a pharmaceutical by using the conventional chemistry knowledge. The motivation stems from the expectation of making compounds having equal or better pharmaceutical agent.

Claiming of a new use, new function or unknown property, which is inherently present in the prior art, does not necessarily make the claim patentable. In re Best, 562 F. 2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). See also MPEP 2141.02.

11. It has been held that a prior art disclosed compounds is sufficient to render a prima facie case of obviousness as species falling within a genus. See In re SUSI, 440 F 2d 442, 169 USPQ 423, 425 (CCPA 1971), followed by Federal Circuit in Merck & co. V. Biocraft Laboratories, 847 F 2d 804, 10 USPQ 2d 1843, 1846 (Fed. Cir.1989). See In re Dillon 16 USPQ 2nd. 1897, 1923 regarding a prima facie case of obviousness of structurally similar compounds disclosed by prior art" regardless to the properties disclosed in the inventor's application.

Conclusion

12. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sudhaker B. Patel, D.Sc.Tech. whose telephone number is (571) 272-0671. The examiner can normally be reached on 6:30 to 5:00 pm (Monday-Thursday). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Mukund J. Shah can be reached on (571) 272 0674 or Sr. Examiner Mr. Richard Raymond at (571) 272 0673 or Mr. James O. Wilson at (571) 272-0661. The fax phone numbers for the organization where this application or proceeding is assigned are 703 308 4556 for regular communications and 703 308 4556 for After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308 1235. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

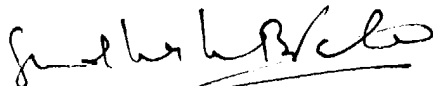
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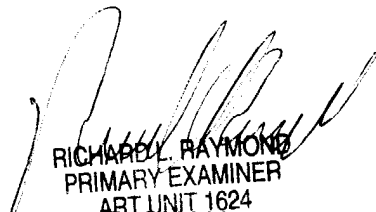
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Sudhaker B. Patel, D.Sc. Tech.
May 3, 2004.



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